IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: KURANO, Yoshihiro et al. Conf.:

Appl. No.: NEW Group:

Filed: December 7, 2001 Examiner:

For: ANTI-ABNORMAL TYPE PRION MONOCLONAL

ANTIBODY, PROCESS FOR PRODUCING THE SAME,

AND IMMUOASSAY USING THE SAME

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents Washington, DC 20231

December 7, 2001

Sir:

The following preliminary amendments and remarks are respectfully submitted in connection with the above-identified application.

AMENDMENTS

IN THE CLAIMS:

Please amend the claims as follows:

4. (Amended) The monoclonal antibody or the antigen-binding fragment thereof according to claim 1, originated from an animal immunized with and immunogen comprising a carrier and a peptide having the amino acid sequence shown in SEQ ID NO: 2.

- fragment thereof according to claim 1 or 5, which is a monoclonal antibody.
- 7. (Amended) A hybridoma which produces the monoclonal antibody according to claim 1 or 5.
- 8. (Amended) A method for measuring abnormal type prion by an immunoassay utilizing said antigen-antibody reaction between said monoclonal antibody according to claim 1 or 5, and an abnormal type prion.
- 10. (Amended) A process for producing the anti-abnormal type prion monoclonal antibody according to claim 1, comprising immunizing an animal with an immunogen including a peptide consisting essentially of a plurality of regions in said abnormal type prion, which regions are discontinuous each other in primary amino acid sequence of said abnormal type prion, and which regions are ligated each other in said peptide; preparing hybridomas originated from antibody-producing cells of the immunized animal; screening a hybridoma which produces an anti-abnormal type prion monoclonal antibody which reacts with said abnormal type prion by antigen-antibody reaction but does not substantially react with

- said normal type prion by antigen-antibody reaction; and recovering said anti-abnormal type prion monoclonal antibody from said hybridoma selected by said screening.
 - 16. (Amended) The anti-abnormal type prion monoclonal antibody which was produced by the process according to claim 10.
 - 17. (Amended) The immunogen used in the process according to claim 10.

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REMARKS

Attached hereto is a marked-up version of the changes made to the application by this Amendment.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

The claims have been amended as follows:

- 4. (Amended) The monoclonal antibody or the antigen-binding fragment thereof according to [any one of claims 1 to 3] <u>claim 1</u>, originated from an animal immunized with and immunogen comprising a carrier and a peptide having the amino acid sequence shown in SEQ ID NO: 2.
- 6. (Amended) The monoclonal antibody or the antigen-binding fragment thereof according to [any one of claims 1 to 5] claim 1 or 5, which is a monoclonal antibody.
- 7. (Amended) A hybridoma which produces the monoclonal antibody according to [any one of claims 1 to 5] claim 1 or 5.
- 8. (Amended) A method for measuring abnormal type prion by an immunoassay utilizing said antigen-antibody reaction between said monoclonal antibody according to [any one of claims 1 to 6] claim 1 or 5, and an abnormal type prion.

- 10. (Amended) A process for producing the anti-abnormal type prion monoclonal antibody according to [any one of claims 1 to 6] claim 1, comprising immunizing an animal with an immunogen including a peptide consisting essentially of a plurality of regions said abnormal type prion, which regions discontinuous each other in primary amino acid sequence of said abnormal type prion, and which regions are ligated each other in said peptide; preparing hybridomas originated from antibodyproducing cells of the immunized animal; screening a hybridoma which produces an anti-abnormal type prion monoclonal antibody which reacts with said abnormal type prion by antigen-antibody reaction but does not substantially react with said normal type prion by antigen-antibody reaction; and recovering said antiabnormal type prion monoclonal antibody from said hybridoma selected by said screening.
- 16. (Amended) The anti-abnormal type prion monoclonal antibody which was produced by the process according to [any one of claims 10 to 15] claim 10.
- 17. (Amended) The immunogen used in the process according to [any one of claims 10 to 15] claim 10.